



<NOTICE>

<PREAMB>

<AGENCY TYPE='S'>DEPARTMENT OF AGRICULTURE
<SUBAGY>Food Safety and Inspection Service
<DEPDOC>[Docket No. FSIS-2012-0032]
<SUBJECT>Testing of Product Samples for Listeria monocytogenes: Changes in Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing changes in procedures for Listeria (L.) monocytogenes product sampling programs in ready-to-eat (RTE) meat and poultry products. Starting 60 days after issuance of this notice, FSIS will increase the number of product samples it collects under its Routine Risk-based L. monocytogenes (RLm) Sampling Program and its Intensified Verification Testing (IVT) protocol from three to five samples per sampling unit. In addition, FSIS laboratories will composite the five 25-g product samples from the RLm sampling program, which will increase the sample size of the analyzed test portion from 25 g to 125 g. The Agency is effecting these changes to make its sampling procedures more consistent with international practices, to conserve its laboratory resources, and to improve public health. FSIS invites comments on these changes to its sampling programs.

DATES: To receive full consideration, comments on this notice should be received by November 23, 2012.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Policy and Program Development, Risk, Innovations, and Management Division, Patriots Plaza 3, 8-163A, 1400 Independence Avenue SW, Mailstop 3782, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0032. Comments received in response to this notice will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Acting Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, telephone (202) 204-0495.

SUPPLEMENTARY INFORMATION:

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) that is intended to ensure that meat, meat food, poultry, and poultry products distributed in commerce are wholesome; not adulterated; and properly marked, labeled, and packaged. As part of its inspection program, FSIS collects samples of these products for laboratory analysis (21 U.S.C. 642(a) and 460(b)).

<HD1>RTE Sampling programs for Listeria monocytogenes

Since the late 1980s, FSIS has been sampling RTE meat and poultry products for the pathogen L. monocytogenes. In 2003, FSIS published the interim final rule, "Control of L. monocytogenes in RTE Meat and Poultry Products" (68 FR 34208; Jun. 6, 2003), which declares that post-lethality exposed RTE products are adulterated if they test positive for L. monocytogenes or come into direct contact with a food-contact surface that tests positive for L. monocytogenes. Post-lethality exposed RTE meat and poultry products include deli meat and hotdog products. Since the rule's implementation, the Agency has moved to more risk-based testing programs to verify the adequacy of an establishment's food safety system, including the measures that an establishment implements for the control of L. monocytogenes.

The RLM sampling program is a risk-based program designed to detect L. monocytogenes contamination from three types of samples: Food-contact surfaces (sampling code: RLMCONT), non-food contact environmental surfaces of equipment and facilities (sampling code: RLMENVC), and post-lethality-exposed RTE product (sampling code: RLMPROD). An Enforcement Investigation and Analysis Officer (EIAO) collects samples for RLM testing in

conjunction with a routine food safety assessment (FSA) to evaluate the food-safety controls in place at an establishment.

Under another risk-based program, IVT, inspectors (or EIAOs) collect follow-up samples if RTE meat or poultry product samples or food-contact surface samples test positive for L. monocytogenes or Salmonella. An IVT, similar to a RLM, is designed to analyze three types of samples: food-contact surfaces (sampling code: INTCONT), non-food contact environmental surfaces (sampling code: INTENV), and post-lethality-exposed RTE product (sampling code: INTPROD). As with RLM sampling, IVT sampling is performed along with an FSA, although this FSA is for-cause as opposed to being routine.

<HD1>Changes to RLMPROD and INTPROD Sampling Procedures

When conducting sampling of post-lethality-exposed RTE product for L. monocytogenes, FSIS personnel randomly collect enough finished product to form a 1-lb sample and ship it to the FSIS laboratory listed on the sample request form. They package and seal the sample using plastic bags provided for the purpose; refrigerate or freeze it; complete the sample request form; and send the sample and the form via a package express service to the

FSIS Field Service Laboratory or other laboratory designated on the sample request form.

From the 1-lb RLMPROD or INTPROD sample it receives, the laboratory draws a 25-g unit which it analyzes according to procedures in the FSIS Microbiology Laboratory Guidebook (MLG) (http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp). The MLG contains procedures for the detection, isolation, confirmation, and identification of L. monocytogenes in meat and poultry samples.

Currently, a sampling unit for both RLM and IVT sampling programs consists of 10 food-contact surface, five non-food-contact environmental surface, and three food product samples. FSIS is not making any changes to its food-contact and non-food contact surface sample testing.

FSIS is planning, however, to change the number of food product samples per sampling unit it collects when sampling for L. monocytogenes from three to five food product samples per sampling unit for both the RLM and IVT programs. (The sampling unit for IVT when sampling for Salmonella [5 product samples, 8 environmental samples, and 5 food contact samples] will not change.) In addition, its laboratories will composite - physically mix - the

five 25-g RLMPROD samples to form a single 125-g analytical unit and then conduct a microbiological analysis on that composited sample (sampling code: RLMPRODC). The Agency will make appropriate changes in the MLG to reflect this new procedure. The laboratories will not composite the five 25-g INTPROD samples because those samples are collected for investigative purposes, and it is necessary for the Agency to know the specific production information related to those individual samples.

To support an increase in the sample size analyzed (from 3 x 25 g, or 75 g per sampling unit, to 5 x 25 g, a total of 125 g per sampling unit), FSIS performed a validation study of the current FSIS L. monocytogenes detection method (MLG Chapter 8). The study showed that, with slight modifications to the laboratory method, there would be no difference in the sensitivity of the method in detecting L. monocytogenes using either 25 g or 125 g of product.

FSIS is initiating these changes to its procedures to make the results of its analyses more comparable with results obtained internationally. Many countries are following the Codex Alimentarius Commission Guidelines on the Application of General Principles of Food Hygiene to

the Control of Listeria Monocytogenes in Ready-to-Eat Foods (CAC/GL-61 (2007)). Annex II of these guidelines (Microbiological Criteria for L. monocytogenes in Ready-to-eat Foods), recommends national governments use a criteria of five product samples for microbiological analysis, with 25-g test portions analyzed per sample. Under these guidelines, national governments have the discretion to decide whether to composite the samples or analyze each individually.

FSIS is also initiating these changes to its procedures to conserve laboratory resources. While FSIS will be collecting more product samples, FSIS expects that compositing five 25-g RLMPROD samples into a single 125-g test portion will reduce the overall number of analyses performed and thus reduce the associated laboratory costs.

Furthermore, FSIS expects that increasing the number of product samples and test portions per sample will have a positive impact on public health because implementing these changes increases the potential for detecting positive samples. For example, from July 2010 to June 2012, with three samples per sampling unit, FSIS tested around 460 INTPROD samples per year. Of those samples, approximately five samples (about one percent of tested samples) were found to be positive for L. monocytogenes.

Assuming the current percent positive detection rate do not change, FSIS expects that when testing around 760 samples per year, approximately eight samples (about one percent of 760 samples) will be found to be positive for L. monocytogenes.¹ Increased detection of adulterated product will reduce the number of illnesses and deaths caused by L. monocytogenes and will also likely improve control for L. monocytogenes in RTE meat and poultry products.

<HD1>Cost-Benefit Analysis for Increasing the Sample Numbers of RLM Product Samples (RLMPROD) and IVT Product Samples (INTPROD) and Compositing RLMPROD Samples Expected Costs

Budgetary Costs to the Agency

If the Agency had increased the number of RLMPROD product samples from three to five per sampling unit but did not decide to composite these samples, there would have been increased costs to FSIS. Agency data shows that the annual number of product samples analyzed is 1,882 for RLMPROD and 432 for INTPROD.² The increase in the number of samples will be around 1,550 $((3,138 - 1,882) + (720 - 432))$, as given in Table 1. However, compositing the

¹ Please also see footnote #5 and #6 below.

² 2009-2010 average. Data from Data Analysis and Integration Group/Office of Data Integration and Food Protection (DAIG/ODIFP).

RLMPROD samples will reduce the number of analyses performed in the RLMPROD sampling program to about 630 (3,138/5), and the total number of analyses the Agency labs will perform annually for RLMPROD and INTPROD will decrease by 964 $[(1,882+432)-(630+720)]$. This reduction in turn will result in decreased costs to the Agency labs.

Sampling Program	Samples per unit	Total # of Sample Analyses
RLMPROD (current)	3	1882
RLMPRODC (proposed composites)	5	630*
INTPROD (current)	3	432
INTPROD (proposed)	5	720

*FSIS projects that the number of RLMPROD samples collected prior to compositing will increase from 1882 to 3138.

The Agency has estimated the savings to the laboratories by reducing the number of sample analyses performed to be approximately \$40,000, which includes savings for expendable supplies such as gloves, plates, etc.³

Costs to the Industry

³ Data from the Laboratory Director, Office of Public Health Science (OPHS), FSIS.

One major cost to the industry will be the likely loss from the additional contaminated RTE products detected by the additional sampling, which the establishments will have to destroy. Even though these adulterated products should be destroyed and not sold to consumers, establishments would have earned revenue selling these products. If additional testing results in more positive samples, more product will need to be discarded and, in turn, yield less revenue for the establishments.

The Agency used the most recent data on the average price of deli meats compiled by FreshLook Marketing Group as a proxy for the price of RTE meat and poultry products, which is \$6.98 per pound.⁴ Agency data on contaminated products found under RLMPROD and INTPROD averaged about 12.6 million lb per year (2008-2011). An accurate value for the real increase in the percent positive rate will be measured after the Agency starts collecting the number of samples as proposed by this notice. For the current analysis, the Agency assumes the percent positive value

⁴ (1) Provided by Ed MacKowiak at FreshLook Marketing Group on July 13, 2011 via personal communication.

(2) Total U.S. traditional grocery store scanner data. Deli meats include deli beef/pork/bacon, bologna, frankfurter, ham, loaves, poultry, salami, sausage, specialty meats/pates, and other. Price is 52-week average as of 6/19/2011.

(3) Most contaminated RTE samples are from deli meats and hotdogs. Therefore, this price index is a reasonable proxy.

will increase in the same proportion as the number of samples increases, which is 67 percent $[(5-3)/3.]^{5,6}$ It follows that the contaminated products would increase to about 21 million pounds - an 8.4 million-pound increase. Multiplying 8.4 million pounds by \$6.98 per pound gives \$58.6 million, which is the possible loss in market value of the additional detected contaminated products.

If establishments that are already testing for L. monocytogenes choose to composite samples, they may incur validation costs at about \$30,000 to \$60,000 each.⁷ However, this cost impact will not be significant for the following reasons: (1) very few establishments are testing for L. monocytogenes; (2) the Agency is not mandating compositing, so the methods change will be voluntary, and establishments will only choose to do so if it is beneficial; and (3) in the long run, those establishments that make the changes to testing composited product samples can recover the validation cost because they will have fewer sample analyses to perform.

Expected Benefits

⁵ Note that this is an upper-bound assumption, implying that all the additional positive samples are from lots that previously tested negative lots, and none is from lots that previously tested positive. The number is likely to be lower than 67 percent, but we will not know what it is likely to be until we implement the change.

⁶ As mentioned above, compositing five 25 g samples to one 125 g test portion will not impact the sensitivity of the tests, thus will not increase the percent positive rate.

⁷ Information from Office of Public Health Science, FSIS.

The main benefit from increasing the sample number is the reduction of illnesses and deaths caused by L. monocytogenes. A recent risk assessment (2012) conducted jointly by FSIS and FDA indicates that any L. monocytogenes on incoming RTE foods, both those that support the growth of L. monocytogenes and those that do not, that are sliced, prepared, or packaged in retail grocery stores contributes to retail cross-contamination of other RTE food sliced, prepared, or packaged at retail and, in turn, contributes to increased risk of listeriosis.⁸ Prior FSIS risk assessments showed that most listeriosis cases attributed to RTE foods were associated with those exposed to the retail grocery environment (e.g., sliced, prepared, or packaged).⁹ Other studies supported these findings.¹⁰ By increasing the number and amount of RTE food product samples being tested for L. monocytogenes, contaminated product can be more readily detected and diverted from going to retail. This result

⁸ U.S. Department of Agriculture, Food Safety and Inspection Service and Food and Drug Administration, Center for Food Safety and Applied Nutrition (2012). Interagency Retail Listeria monocytogenes Risk Assessment. Washington, DC.

⁹ Endrikat S, Gallagher D, Pouillot R, et al. A comparative risk assessment for Listeria monocytogenes in prepackaged versus retail-sliced deli meat. J Food Prot 2010;73:612-9.

¹⁰ Pradhan AK, Ivanek R, Gröhn YT, et al. Quantitative risk assessment of listeriosis-associated deaths due to Listeria monocytogenes contamination of deli meats originating from manufacture and retail. J Food Prot 2010;73:620-30.

reduces the risk of listeriosis both from the contaminated RTE product being diverted and from other RTE foods that could become cross-contaminated by these products during retail slicing, preparation, or packaging operations.

According to the most recent CDC analysis, there are about 1,591 (with a range of 557 to 3,161) domestically-acquired foodborne illnesses caused by L. monocytogenes annually. The average annual number of hospitalization, is 1,455 (with a range of 521 to 3,018), and the average number of deaths is 255 (with a range of 0 to 733).¹¹

Using this information and an ERS (Economic Research Services) model, the Agency has recently updated the cost of illnesses of L. monocytogenes to be \$1.3 million per case in 2010 dollars. This estimate represents a lower bound for an average cost of L. monocytogenes because it only includes medical costs and loss-of-productivity costs. It does not include pain and suffering costs.

The Agency's analysis suggests that the new sampling will reduce the number of illnesses by an average of 90 cases per year (with a range of 3 to 134).¹² This number does not include the reduced illnesses from reduced cross-contamination at retail, so the number could be higher.

¹¹ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M, Roy SL, Jones JL, and Griffin PM. 2011. Foodborne illness acquired in the United States -- major pathogens. Emerg Infect Dis, 17(1):7-11.

¹² Analysis results are from the Risk Assessment Division, OPHS.

Multiplying the average number of reduced illnesses by the average cost per case results in reduced illness benefits of about \$117 million annually.

The Agency also expects that with the increased sampling, the establishments will strengthen their own L. monocytogenes control measures, which will further reduce the number of illnesses. However, FSIS cannot quantify this impact with any precision.

Net benefits

As explained in the Expected Costs and Expected Benefits Sections, there are uncertainties in the Agency's cost and benefit estimates. Consequently, it is very difficult to arrive at a concrete estimate of net benefits. The biggest uncertainty is that FSIS cannot accurately predict the amount of adulterated product that will be detected as a result of increasing the sampling numbers. The Agency can only estimate the amount with some strong assumptions. The Agency believes that it can have a reasonable net benefit estimate by adding the estimated benefits from reduced illnesses (\$117 million), then subtracting the cost to the industry (\$58.6 million). The result is a net benefit of about \$58.33 million annually.

The changes in FSIS's sampling procedures do not impose a testing requirement on official establishments.

Therefore, these changes will not have a negative effect on small or very small establishments.¹³

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at 202-720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

¹³ Based on FSIS's HACCP (Hazard Analysis and Critical Control Points) size definition: very small establishments have fewer than 10 employees or generate less than \$2.5 million in annual sales; and small establishments have 10 or more but fewer than 500 employees and generate more than \$2.5 million in annual sales.

FSIS will announce this notice on-line through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_&_Events/Email_Subscription/. Options range from recalls to export information to

regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done in Washington, DC, on: September 18, 2012

Alfred V. Almanza

Administrator.

<FRDOC> [FR Doc. 2012–23462 Filed

9–21–12; 8:45 am]

<BILCOD>BILLING CODE 3410–DM–P

[FR Doc. 2012-23462 Filed 09/21/2012 at 8:45 am;
Publication Date: 09/24/2012]